REMARKS

The Office Action mailed August 8, 2007 has been received and reviewed. In the Office Action, claims 49-62 were pending in the subject application. More specifically, claims 49-59 stand rejected under 35 U.S.C. § 112, ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claims 49-57 and 59-62 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,317,719 to Schrier et al. (hereinafter the "Schrier reference") in view of U.S. Patent No. 6,070,761 to Bloom et al. (hereinafter the "Bloom reference") and in further view of U.S. Patent No. 6,112,182 to Akers et al. (hereinafter the "Akers reference"). Further, claim 58 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the Schrier reference in view of the Bloom reference and the Akers reference and in further view of U.S. Patent No. 5,845,255 to Mayaud (hereinafter the "Mayaud reference"). Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested.

Rejections based on 35 U.S.C. § 112, ¶ 2

Claims 49-59 stand rejected under 35 U.S.C. § 112, ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Independent claims 49 and 54 have been amended herein to resolve this informality and, as amended, particularly point out and distinctly claim the subject matter. Specifically, independent claim 49 has been amended to state "presenting a user with one or more alternative drugs based at least in part on one of the querying steps," indicating that the alternative drugs may be based on either, or both, of the recited querying steps. Similarly, independent claim 54 has been amended to state "presenting a user with one or more alternative drugs based at least in part on one of the identifying steps," indicating that the alternative drugs

may be based on either, or both, of the recited identifying steps. Applicants respectfully submit that, as amended, independent claims 49 and 54 overcome the 35 U.S.C. § 112, ¶ 2 rejection. Each of claims 50-53 and 55-59 depends, either directly or indirectly, from one of independent claims 49 and 54 and, thus, the amendments to the independent claims overcome the 35 U.S.C. § 112, ¶ 2 rejection of these claims as well. Thus, Applicants respectfully request that the 35 U.S.C. § 112, ¶ 2 rejection of claims 49-59 be withdrawn.

Rejections based on 35 U.S.C. § 103(a)

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The Supreme Court in *Graham v. John Deere* counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in *Graham* and to provide some reason, or suggestion or motivation found either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art reference or to combine prior art reference teachings to produce the claimed invention. See, *Application of Bergel,* 292 F. 2d 955, 956-957 (1961). Thus, in order "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference

or to combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." *See* MPEP § 2143. Recently, the Supreme Court elaborated, at pages 13-14 of *KSR*, it will be necessary for [the Office] to look at interrelated teachings of multiple [prior art references]; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the [patent application]." *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

Claims 49-57 and 59-61 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Schrier reference in view of the Bloom reference and in further view of the Akers reference. As none of the Schrier reference, the Bloom reference and the Akers reference, either alone or in combination, teach or suggest all of the claim limitations of independent claims 49, 54, and 60, Applicants respectfully traverse this rejection as hereinafter set forth.

As previously presented, independent claim 49 recites a method of managing the pharmaceutical care of a patient using one or more software-accessible databases which comprises, in part, querying the clinical database with a selection, by a clinician, of a disease state to be treated *from a list of one or more existing disease states* associated with the patient. As stated in the specification, "[a]ll other disease states of the patient (from the patient diagnostic profile) and all allergies of the patient (from the patient's allergy profile) are automatically listed in the patient's underlying conditions." *Specification*, at p. 21, lines 12-20.

As the Applicants have previously submitted, the Schrier reference fails to teach or suggest a method of managing care in which the clinician manages a condition having

knowledge and context of a number of other conditions. *See generally Schrier reference.* Instead, the Schrier reference discloses a data processing system providing users with various information associated with a specific drug. *See, e.g., Schrier reference* at col. 3, lines 35-48. The data processing system includes specific drug information such as identification of concomitant drugs, drug allergies, and drug interactions. *See, e.g., Schrier reference* at col. 3, lines 29-34. But the Schrier reference does not teach or suggest presenting the clinician with a list of one or more disease states and querying the clinical database with a selection of a disease state, thus presenting the clinician with knowledge of various other patient conditions.

The Applicants' point of distinction is illustrated by the portion of the Schrier reference cited by the Examiner as teaching this limitation. *See Schrier reference* at col. 8, lines 36-51. In that portion, the Schrier reference discloses that the system may require information about the patient's clinical condition *from the clinician. See id.* For instance, the system may query the clinician to identify the condition for which the drug will be used, the condition's severity, etc. *See id.* Thus, the Schrier reference queries the clinician to obtain patient information from the clinician, giving the system context for the clinician's intended use for a particular drug. This is, indeed, the *opposite* of the requirements of claim 49, which require that the clinician is presented with contextual information, instead of being prompted to provide it. And claim 49 requires that the clinician query the clinical database, instead of having the database querying the clinician. Where the system of the Schrier takes contextual information from the clinician, the method of claim 49 provides contextual information to the clinician. Neither the Bloom reference nor the Akers reference overcomes the deficiencies of the Schrier reference. Thus, Applicants respectfully submit that the Schrier reference, the Bloom reference, and the Akers reference, either alone or in combination, fail to teach or suggest each of the

limitations of currently amended independent claim 49. Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of this claim.

With reference to independent claim 54, as currently amended, a method of managing the pharmaceutical care of a patient using one or more software-accessible databases is recited which comprises, in part, identifying, with a selection by a clinician, a disease state to be treated *from a list of one or more existing disease states* associated with the patient. As previously stated, none of the Schrier reference, the Bloom reference, and the Akers reference, either alone or in combination, teach or suggest a clinician managing a condition having knowledge of a number of other conditions. Thus, Applicants respectfully submit that the Schrier reference, the Bloom reference, and the Akers reference, either alone or in combination, fail to teach or suggest each of the limitations of independent claim 54 under 35 U.S.C. § 103(a). Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of this claim.

With reference to independent claim 60, a method for identifying one or more drugs causing an identified adverse reaction using one or more software-accessible databases is recited which comprises, in part, querying the clinical database *with a given adverse reaction.* As stated in the specification, the adverse reaction query is "used to produce a list of therapeutic drug classes and selectively identify members of each therapeutic class and the likelihood to which they might cause a given adverse reaction." *Specification*, at p. 24, lines 3-15. The adverse reaction query is capable of being performed independent of any patient information and, where a patient is not involved in the query, "[a] list is prepared comprising all drugs in the selected class that have associated therewith at least one of the [adverse reactions]." *See id.*

As the Applicants have previously submitted, the Schrier reference is patient-centric and discloses a patient-specific drug information. *See, e.g., Schrier reference* at col. 3, lines 35-48. Further, the Schrier reference fails to teach or suggest a query based on a *given adverse reaction*. *See generally Schrier reference*. Applicants respectfully submit that the portion of the Schrier reference cited by the Examiner as meeting this limitation is yet another example of the patient-centric nature of the Schrier reference. *See Schrier reference* at Col. 9, lines 4-17. Indeed, the portion of the reference cited by the Examiner notes that the reference is "patient-specific" *See Schrier reference* at Col. 9, lines 1-3. The Schrier reference does not teach or suggest a patient-agnostic adverse reaction query that provides a clinician with drug information for a drug that is not already associated with a patient. *See generally Schrier reference*. The Schrier reference only teaches querying based on a particular patient. *See id.* Neither the Bloom reference nor the Akers reference overcomes the deficiencies of the Schrier reference. Thus, Applicants respectfully submit that the Schrier reference, the Bloom reference, and the Akers reference, either alone or in combination, fail to teach or suggest each of the limitations of currently amended independent claim 60. Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of this claim.

With reference to independent claim 62, a method for comparing drugs in a therapeutic class using one or more software-accessible databases is recited which comprises, in part, querying the clinical database with a drug class or a drug subclass. Similar to independent claim 60, the Schrier reference fails to teach or suggest the limitations of independent claim 62 because the Schrier reference does not teach or suggest querying based on a drug class or a drug subclass. Applicants respectfully note that the Examiner did not address this limitation of claim 62, instead relying on the rejection of claim 49 to reject this claim. But even if it were addressed,

this limitation is not taught or suggested by the Schrier reference. Instead, the Schrier reference is patient-centric and discloses a patient-specific drug information. *See, e.g., Schrier reference* at col. 3, lines 35-48. Just as the Schrier reference fails to teach or suggest a query based on an adverse reaction for claim 60, the reference also fails to teach or suggest a query based on a drug class or drug subclass in this claim. *See generally Schrier reference*. The Schrier reference does not teach or suggest a patient-agnostic drug class or subclass query that provides a clinician with drug information for a drug that is not already associated with a patient. *See generally Schrier reference*. The Schrier reference only teaches querying based on a particular patient. *See id.* Neither the Bloom reference nor the Akers reference overcomes the deficiencies of the Schrier reference. Thus, Applicants respectfully submit that the Schrier reference, the Bloom reference, and the Akers reference, either alone or in combination, fail to teach or suggest each of the limitations of currently amended independent claim 62. Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of this claim.

Each of claims 50-53, 55-57, 59, and 61 depends, either directly or indirectly, from one of independent claims 49, 54, and 60. Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness based upon the Schrier reference, the Bloom reference, and the Akers reference, either alone or in combination, cannot be established for these claims for at least the same reasons as cited above. "'If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.' *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)." MPEP § 2143.03. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 50-53, 55-57, 59, and 61 is respectfully requested as well.

Claim 58 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the Schrier reference in view of the Bloom reference and the Akers reference and in further view of

the Mayaud reference. As none of the Schrier reference, the Bloom reference, the Akers reference, and the Mayaud reference, either alone or in combination, teach or suggest all of the claim limitations of claim 58, Applicants respectfully traverse this rejection as hereinafter set forth.

Claim 58 depends from allowable claim 54 and, thus, should be allowable for at least the reasons cited above. More particularly, as previously stated, the Schrier reference, the Bloom reference, and the Akers reference, either alone or in combination fail to teach or suggest a clinician managing a condition having knowledge of a number of other conditions, as required by independent claim 54. The addition of the Mayaud reference does not cure this deficiency. More specifically, the prescription creation system of the Mayaud reference fails to teach or suggest a clinician managing a condition having knowledge of a number of other conditions. Instead, the Mayaud reference discloses fulfillment information and alerts where an expiration date has passed without a subscription being filled. *See Mayaud reference*, col. 28, lines 30-49. Thus, Applicants respectfully submit that the Schrier reference, the Bloom reference, the Akers reference, and the Mayaud reference, either alone or in combination, fail to teach or suggest each of the limitations of claim 58 under 35 U.S.C. § 103(a). Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of this claim.

CONCLUSION

For at least the reasons stated above, claims 49-62 are in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of claims 49-62. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned by telephone prior to issuing a subsequent action.

A two-month extension fee is believed due and is submitted herewith. No other fee is believed due in connection with this Amendment, but the Commissioner is hereby authorized to charge any additional amount required or to credit any overpayment to Deposit Account No. 19-2112 and referencing Attorney Docket No. CRNI.134923.

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Respectfully submitted,

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